

DOCKET NO: 274296US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
KAZUSHI OSHINO, ET AL. : EXAMINER: ROBERTS, LEZAH  
SERIAL NO: 10/540,266 :  
FILED: DECEMBER 7, 2005 : GROUP ART UNIT: 1612  
FOR: ORAL PREPARATION SYSTEM :

DECLARATION UNDER 37 C.F.R §1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Mr. Atsushi Yamagishi who deposes and states that:

1. I am a graduate of the Graduate School of Nagaoka University of Technology, Materials Science and Technology, and received my Master's degree in the field of Materials Science and Technology, in the year 1988.
2. I have been employed by Kao Corporation, for 20 years involved in research and development of hair care products from 1988 to 1999 and then involved in research and development of oral products from 1999 to present.
3. The following experiments were carried out by me or under my direct supervision and control.
4. The following experiments demonstrate that, surprisingly, the amount of fluorine adsorption is extremely decreased by adding a phosphate compound (dipotassium phosphate)

to the compound (B) which is a fluoride ion supplying compound other than a monofluorophosphate ion supplying compound.

5. The testing method is the same as the method disclosed in the Examples of the specification.

6. The HAP pellet was immersed alternatively three times in A and B agents of 10 ml each (total immersion time: 3 minutes). The immersion (treating) method is the same as the method disclosed in “b. Quantitative Determination of Amount of Fluorine Adsorption on HAP Pellet” of the specification.

7. The experiment was conducted at pH7.

8. The content of phosphoric acid in Comparative Example B1 is the same as that of the phosphate ion supplying compound in Example 6 of Winston. In Comparative Example B2, a ratio of calcium ions to phosphate ions is made close to that of Example 6 in Winston. In Comparative Example B3, the phosphate ion concentration is further lowered and gets closer to 1,000 ppm.

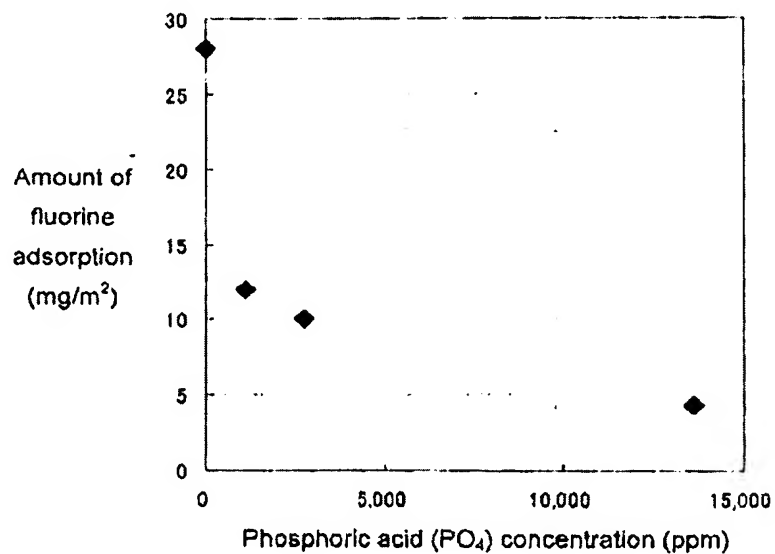
Component (wt%)	Example B1		Comparative Example B1		Comparative Example B2		Comparative Example B3	
	A	B	A	B	A	B	A	B
Calcium glycerophosphate	0.5	--	0.5	--	0.5	--	0.5	
Calcium lactate	0.5	--	0.5	--	0.5	--	0.5	
Sodium monofluorophosphate	0.7	--	0.7	--	0.7	--	0.7	
Sodium fluoride	--	0.2	--	0.2	--	0.2	--	0.2
Dipotassium phosphate	--	--	--	2.5	--	0.5	--	0.2
Purified water	Balance							
Total	100	100	100	100	100	100	100	100
Amount of fluorine adsorption (mg/m <sup>2</sup> )	28		4.3		10		12	

Phosphoric acid (PO <sub>4</sub> ) concentration (ppm)	--	13,635	2,727	1,090
Phosphoric acid (PO <sub>4</sub> ) concentration (μmol/g)	--	440	88	35

In the calculation of phosphoric acid concentration, 1L solution was regarded as 1 kg.  
Calcium: About 40 μmol/g

9. It is clear from the results that the amount of fluorine adsorption is extremely decreased by adding a phosphate compound (dipotassium phosphate) to the compound (B).

10. The graph below shows the relationship between the phosphoric acid (PO<sub>4</sub>) concentration (ppm) and the amount of fluorine adsorption (mg/m<sup>2</sup>) based on the conducted experiments.



12. The claimed oral preparation provides an advantageous result.

Application No. 10/540,266  
Declaration under 37 CFR 1.132

13. Under penalty of perjury under the laws of the United States of America that the foregoing is believed to be true and correct.

Atsushi Yamagishi

Atsushi Yamagishi

November 9, 2009

Date